UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

United States of America,

Plaintiff, Case No. 1:17cr050

v. Judge Michael R. Barrett

Barbara Temeck,

Defendant.

OPINION & ORDER

This matter is before the Court upon Defendant Barbara Temeck's Motion for Acquittal or, in the Alternative, for New Trial as to Count 3 of the Indictment and Motion for Reconsideration of the Court's Order denying Defendant's Motion to Dismiss for Selective Prosecution. (Doc. 71). The Government has filed a Response in Opposition (Docs. 77 & 80). On June 7, 2018, the Court held oral argument on Defendant's Motion. (Doc. 89).

I. BACKGROUND

Defendant stood trial on three counts of violations of the Controlled Substances Act, 21 U.S.C. § 841(a)(1). The Controlled Substances Act contains general prohibitions involving the illegal manufacturing, distribution, dispensing, or possessing of controlled substances. To possess or dispense a controlled substance, physicians must be licensed to practice medicine and register annually with the Drug Enforcement Administration ("DEA"). 21 U.S.C. § 822. It is well-settled law that even physicians who register still may be convicted for violations of the Controlled Substances Act if the drugs prescribed were

without legitimate medical purpose and outside the course of professional practice. *United States v. Elliott*, 876 F.3d 855, 865 (6th Cir. 2017).

Defendant is the former Chief of Staff at the Cincinnati VA Medical Center and was employed by the U.S. Department of Veterans Affairs' Veterans Health Administration ("VA") for approximately thirty-five years. (Doc. 81, PAGEID# 1146). Defendant is board certified in general surgery and thoracic surgery. (Doc. 81, PAGEID# 1146). It is undisputed that Defendant is a licensed physician.[1] Defendant was issued a fee-exempt DEA Controlled Substance Registration through the VA. (Gov't. Exs. 5-6).

The charges brought against Defendant arose out of three prescriptions Defendant allegedly wrote for one person: K.H. K.H. is a former employee of the VA, married to a high-ranking administrator at the VA, and was seeking treatment as a result of injuries she sustained while employed by the VA. Since approximately 2002, Defendant acted as a "care coordinator" for K.H., which meant Defendant accompanied K.H. when she went to doctor's appointments and also sought referrals for K.H. to be seen by other physicians.[2] Even though K.H. was not treated at a VA facility, a number of these physicians were affiliated with the VA. (Doc. 87, PAGEID# 1483). These physicians prescribed controlled and noncontrolled substances for K.H. (Doc. 87, PAGEID# 1483). The prescriptions for controlled substances are recorded in the Ohio Automated Rx Reporting System ("OARRS"). (Doc. 82, PAGEID# 1312). OARRS is a prescription monitoring system. (Doc. 82, PAGEID# 1312). When a prescription for a controlled

[1]Defendant is licensed to practice medicine in the District of Columbia, Maryland, Virginia, Washington and Illinois. (Doc. 81, PAGEID# 1142).

[2]As care coordinator, Defendant was acting under a health care power of attorney for K.H. (Doc. 67, PAGIED# 1001).

substance is filled, the pharmacist enters information about the patient and the prescription into a database. (Doc. 82, PAGEID# 1312). Law enforcement and healthcare professionals have access to the database. (Doc. 82, PAGEID# 1312). Law enforcement uses the information to prevent diversion of prescriptions for controlled substances. (Doc. 82, PAGEID# 1312). Healthcare professionals use the information to monitor a patient's prescriptions for controlled substances. (Doc. 82, PAGEID# 1314).

At the conclusion of the Government's case, Defendant moved for a judgment of acquittal due to insufficient evidence pursuant to Rule 29 of the Federal Rules of Criminal Procedure. The Court reserved ruling on the motion. (Doc. 55). Defendant orally renewed her motion before submission to the jury. The Court reserved ruling in part, but also granted the motion in part. (Doc. 56). This ruling was made during the charge conference and is reflected in the Court's instructions to the jury.[3]

The jury was instructed that it could find Defendant guilty of a violation of the Controlled Substances Act if the Government proved beyond a reasonable doubt each of the following elements:

> First, the defendant distributed or dispensed a controlled substance as alleged in these counts of the Indictment;
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> Second, the defendant acted knowingly and intentionally in distributing or dispensing that controlled substance;

[3]Because no evidence was presented as to whether the drugs in Counts 1 and 2 were prescribed for a legitimate medical purpose in the usual course of professional practice, the Court instructed the jury that as to Counts 1 and 2 as follows: "I instruct you as a matter of law that your inquiry is limited to the allegation that the defendant wrote prescriptions and she knew she was not authorized to write those prescriptions by her registration." (Doc. 58, PAGEID# 805). While the docket entry erroneously states that the Court denied Defendant's motion in part (Doc. 56), the Court's ruling on this issue was instead reserved as to Count 3. Therefore, following trial, Defendant filed additional authority regarding insufficiency of expert opinion testimony to sustain a conviction on Count 3. (Doc. 66).

> And, third, the defendant knew the act was not authorized by her registration, or if the act was authorized by her registration, the act was knowingly and intentionally not for a legitimate medical purpose.

(Doc. 58, PAGEID# 803).[4]

The jury acquitted Defendant on Counts 1 and 2; and found Defendant guilty on Count 3. Count 3 charges that in November of 2013 Defendant did knowingly, intentionally and unlawfully distribute and dispense a mixture and substance containing a detectable amount of Diazepam, a Schedule IV controlled substance, in violation of federal law. Diazepam is also known by its generic name, Valium. At trial, Defendant testified that on November 2, 2013, she wrote a prescription for Diazepam for K.H. (Doc. 81, PAGEID# 1237). Defendant explained that on that date, which was a Saturday, Defendant was called to the home of K.H. (Doc. 81, PAGEID# 1237). Defendant explained further that K.H. was having an anxiety or panic attack, and Defendant wrote the prescription to help alleviate her symptoms. (Doc. 81, PAGEID# 1237-1239).

Following trial, Defendant timely filed the present Motion pursuant to Rules 29(c) and 33(a) of the Federal Rules of Criminal Procedure. Defendant seeks relief from the Court in the form of either a new trial or an acquittal. Defendant maintains: (1) the government misstated the law and evidence in closing arguments; (2) the jury was erroneously instructed that Defendant could be found guilty on alternate grounds; (3) the

[4]These instructions were based upon *United States v. Blanton*, 730 F.2d 1425 (11th Cir. 1984). In *Blanton*, the district court charged the jury that the defendant could be convicted of a violation of 21 U.S.C. § 841(a)(1) if the jury found either that the defendant (1) "dispensed methaqualone knowing he was not registered for that drug, or (2) if they concluded that he was registered, that he dispensed methaqualone for other than a legitimate medical purpose." *Id*. at 1431.

evidence was insufficient; and (4) the jury's verdict on Count 3 was not unanimous.[5] (Doc. 71, PAGEID# 1020).

II. ANALYSIS

A. Standard of review

Federal Rule of Criminal Procedure 29(a) provides: "After the government closes its evidence or after the close of all the evidence, the court on the defendant's motion must enter a judgment of acquittal of any offense for which the evidence is insufficient to sustain a conviction." Rule 29(b) permits judges to reserve ruling on motions for judgment of acquittal, including motions made at the close of the government's case-in-chief. *See* Fed. R. Crim. P. 29(b) ("The court may reserve decision on the motion, proceed with the trial (where the motion is made before the close of all the evidence), submit the case to the jury, and decide the motion either before the jury returns a verdict or after it returns a verdict of guilty or is discharged without having returned a verdict."). However, as the Sixth Circuit has noted, "Rule 29(b) mandates that when a judge reserves ruling on a motion for judgment of acquittal, the court 'must decide the motion on the basis of the evidence at the time the ruling was reserved,' even if the defendant has put on evidence in his or her own defense." *United States v. Wagner*, 382 F.3d 598, 611, n.2 (6th Cir. 2004).

Following a jury verdict of guilty, Federal Rule of Criminal Procedure 29(c) permits the defendant to renew his or her motion for a judgment of acquittal. *See* Fed.R.Crim.P. 29(c). When reviewing a motion under Rule 29(c), this Court "must decide whether, after viewing the evidence in a light most favorable to the government, any rational trier of fact

[5]The Court addressed Defendant's fourth argument as part of its ruling on Motion for New Trial and for Judicial Inquiry. (Doc. 74).

could have found the essential elements of the crime beyond a reasonable doubt." *United States v. Gardner*, 488 F.3d 700, 710 (6th Cir. 2007) (citing *United States v. Humphrey*, 279 F.3d 372, 378 (6th Cir. 2002)). This Court must not "weigh the evidence, consider the credibility of witnesses, or substitute its judgment for that of the jury." *United States v. Chavis*, 296 F.3d 450, 455 (6th Cir. 2002) (quoting *United States v. Ferguson*, 23 F.3d 135, 140 (6th Cir. 1994)).

If this Court grants a motion under Rule 29(c), this Court must also "conditionally determine whether any motion for a new trial should be granted if the judgment of acquittal is later vacated or reversed." Fed. R. Crim. P. 29(d)(1); *see also United States v. Mikell*, 84 Fed.Appx 485, 489 (6th Cir. 2003) (explaining the district court erred in finding pending motion for a new trial moot after granting motion for acquittal).

A new trial should be granted whenever "the interest of justice so requires." Fed. R. Crim. P. 33(a). However, "[t]he rule does not define interest of justice and the courts have had little success in trying to generalize its meaning." *United States v. Munoz*, 605 F.3d 359, 373 (6th Cir. 2010) (internal quotation marks and citation omitted). "The paradigmatic use of a Rule 33 motion is to seek a new trial on the ground that 'the [jury's] verdict was against the manifest weight of the evidence.'" *Id*. (quoting *United States v. Crumb*, 187 Fed.Appx 532, 536 (6th Cir. 2006)).

In addition, it is "widely agreed that Rule 33's 'interest of justice' standard allows the grant of a new trial where substantial legal error has occurred." *Id*. This would include "reversible error or violation of the defendant's substantial rights." *Id*. at 374. "[L]ess clear is whether a district court may grant Rule 33 relief where the verdict is not against the substantial weight of the evidence, and where no reversible error or violation of the

defendant's substantial rights has occurred, but where the district court nonetheless believes that 'the interest of justice' requires a new trial." *Id*. at 374. Defendant argues that relief under Rule 33 is appropriate based on the cumulative effect of various errors and defects which rendered her trial fundamentally unfair. (Doc. 71, PAGEID# 1035) (citing *United States v. Knox*, 17 Fed.Appx. 353 (6th Cir. 2001)). However, the Sixth Circuit has not answered the question of whether Rule 33 relief may be granted "based on amorphous claims of trial unfairness that do not constitute reversible error." *United States v. Munoz*, 605 F.3d at 375. Accordingly, this Court will analyze Defendant's motion for a new trial solely based on manifest-weight-of-the-evidence grounds.

As the Sixth Circuit has explained:

> Generally, such motions are granted only "in the extraordinary circumstances where the evidence preponderates heavily against the verdict." *United States v. Turner*, 490 F.Supp. 583, 593 (E.D. Mich. 1979), *aff'd*, 633 F.2d 219 (6th Cir. 1980). A district judge, in considering the weight of the evidence for purposes of adjudicating the motion for new trial, may act as a thirteenth juror, assessing the credibility of witnesses and the weight of the evidence. *United States v. Lutz*, 154 F.3d 581, 589 (6th Cir. 1998).

United States v. Hughes, 505 F.3d 578, 592-93 (6th Cir. 2007); *see also United States v. Lutz*, 154 F.3d 581, 589 (6th Cir. 1998) ("A reversal based on the verdict being against the manifest weight of the evidence is proper when the government has presented sufficient evidence to convict, but the judge disagrees with the jury's resolution of conflicting evidence.") (citing *Tibbs v. Florida*, 457 U.S. 31, 42, 102 S.Ct. 2211, 72 L.Ed.2d 652 (1982)).

With those standards in mind, the Court now turns to Defendant's Motion for Acquittal under Rule 29.

B. Motion for Acquittal

As explained above, the jury was instructed that it could find Defendant guilty of a violation of 21 U.S.C. § 841(a)(1) if the Government proved beyond a reasonable doubt each of the following elements:

> First, the defendant distributed or dispensed a controlled substance as alleged in these counts of the Indictment;
>
> Second, the defendant acted knowingly and intentionally in distributing or dispensing that controlled substance;
>
> And, third, the defendant knew the act was not authorized by her registration, or if the act was authorized by her registration, the act was knowingly and intentionally not for a legitimate medical purpose.

(Doc. 58, PAGEID# 803). Therefore, Defendant could be convicted under one of two theories: (1) Defendant wrote the prescription for K.H. "knowing that she was not authorized by her registration" to do so; or (2) Defendant was authorized, but Defendant wrote the prescription for K.H. without a legitimate medical purpose.

As to the first theory, Defendant argues that the evidence presented by the Government was clearly insufficient for a reasonable juror to find, beyond a reasonable doubt, that Defendant knew that she was not authorized to write the prescription for the controlled substance in question to K.H. As to the second theory, Defendant argues that the Government failed to present expert opinion testimony on whether the prescription for K.H. was without legitimate medical purpose.

The first theory, or the "registration" theory, is based upon *United States v. Blanton*, 730 F.2d 1425 (11th Cir 1984). In *Blanton*, the Eleventh Circuit upheld the defendant's conviction based on evidence which established the defendant dispensed the controlled

substance knowing that the defendant was not registered for the drug. *Id*. at 1431. The evidence was as follows:

> In March, 1976, Blanton was first contacted by the DEA. At that time, he was registered to handle substances in Schedules II through V including Schedule II N. The DEA had become concerned because of the unusually large quantities of methaqualone defendant had been purchasing. DEA Investigator Chaves conducted an audit of defendant's methaqualone supply and found that he had 63,500 tablets on hand. When questioned [by the DEA] about why he needed so much methaqualone, defendant said he was doing research. He failed to produce any satisfactory records of that research. Investigator Chaves explained [to him] what type of records must be maintained by researchers. Defendant promised to comply.
>
> When Blanton renewed his DEA registration for 1976-77 in July of 1976, he omitted Schedule II N, which was the methaqualone schedule, and all less dangerous drug schedules from his registration application, checking only the box for Schedule II narcotic substances. Despite his failure to register Schedule II N on his 1976-77 DEA registration, Blanton continued to order large quantities of methaqualone. As a result, he received a visit from investigator Chaves in October 1976. Chaves informed the defendant that he was not registered to handle methaqualone and requested that he immediately register in Schedule II N. Defendant disregarded Chaves's instructions but continued ordering methaqualone. Between November 19, 1976 and October 10, 1977, defendant purchased 294,000 methaqualone tablets from pharmaceutical houses.
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> When defendant renewed his DEA registration for the year 1977-78, he again omitted Schedule II N from his registration application. This prompted a third visit from investigator Chaves on October 7, 1977. Defendant told Chaves that his failure to register for Schedule II N was a "clerical error." Chaves explained to the defendant the procedure for registering and cautioned him not to dispose of the methaqualone in his possession.
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> An audit of defendant's supply five weeks later revealed 92,000 tablets. At that time, Chaves again warned defendant not dispose of the methaqualone because he was not properly registered. A subsequent search of his medical files revealed no record of how defendant disposed of the almost 300,000 tablets he had procured over the previous year and a half.
>
> On December 5, 1977, defendant called William Lenck, who was then an executive assistant to the Administrator of the DEA. In a rambling conversation with Lenck, defendant said that he had not checked all the blocks on his registration application because "it would reveal information concerning research projects that he did not want to be revealed."

> Defendant also disclosed that 3,000 persons were involved in his present project. This conflicted with a statement he had made earlier to a DEA attorney, when he claimed to have between fourteen and thirty thousand persons in his project.
>
> Shortly thereafter, defendant was observed emptying the safe deposit boxes where he stored his supply of methaqualone. Defendant was promptly arrested. Only 16,500 out of the 92,000 tablets noted in the latest audit were found by the police.

Id. at 1428-29. The Eleventh Circuit ruled that viewing this evidence in light most favorable to the government, a reasonable trier of fact could find the evidence established that the defendant was guilty beyond a reasonable doubt. *Id*. at 1430-31. The court pointed to the two occasions on which the defendant failed to check the box which would register him for prescribing Schedule II drugs. *Id*. at 1431. The court also noted that a DEA agent specifically told the defendant that he was not registered for methaqualone, but he continued to order and dispense the drug. *Id*. The court explained that this evidence was coupled with the evidence that despite DEA orders to leave the drugs intact, the defendant attempted to remove his supply of drugs from safe deposit boxes located in three different banks. *Id*. The court concluded that based on this evidence, the jury could reasonably conclude that the defendant ordered more and more methaqualone knowing he was not licensed to do so. *Id*.

The evidence of Defendant's knowledge in the instant case pales in comparison. The Court views the evidence at the time the ruling on Defendant's Rule 29 Motion was reserved. Defendant was convicted based on one prescription written to one patient. When a DEA agent met with Defendant and informed Defendant of her registration limitation, she voluntarily surrendered her registration. (Doc. 83, PAGEID# 1352-1353). Absent from this case is the volume of prescriptions or the multiple warnings from

authorities which the court in *Blanton* found could establish knowledge on the part of the defendant.

The Court acknowledges that "circumstantial evidence may support a guilty verdict, even if the circumstantial evidence is inconclusive." *United States v. White*, 932 F.2d 588, 590 (6th Cir. 1991) (citing *United States v. Stone*, 748 F.2d 361, 362-63 (6th Cir. 1984)). The Government presented evidence that Defendant's DEA registration was mailed to her and the registration certificate includes the following language: "This registration is only for use at Federal or State institutions." (Gov't Ex. 5). However, the Government did not present evidence that Defendant read that language or understood that as a licensed physician she was prohibited from writing a prescription for a controlled substance for K.H.

The Government also presented evidence which would indicate that when Defendant wrote the November 2, 2013 prescription for Diazepam for K.H., Defendant removed the words "To Be Filled in VA Pharmacies Only" from the prescription form. (Doc. 86, PAGEID# 1441; Gov't Exs. 3 & 4). However, the Court notes that the words "To Be Filled in VA Pharmacies Only" has no bearing on whether Defendant was or was not authorized to write a prescription for controlled substances for K.H. Instead, the words "To Be Filled in VA Pharmacies Only" is a restriction on where the prescription could be filled. To that point, the Government also presented evidence of prescriptions Defendant wrote for K.H. for two leg elevators for a wheelchair and physical therapy. (Gov't Exs. 13, 14). These prescriptions were written on what appears to be the same form, and the words "To Be Filled in VA Pharmacies Only" also does not appear on these prescriptions. Therefore, Defendant removed the words "To Be Filled in VA Pharmacies Only"

regardless of whether she was writing a prescription for K.H. for a controlled substance, or writing a prescription for something which was not controlled, such as the medical equipment or the physical therapy.

Finally, the Government presented evidence that in October of 2013 Defendant sought assistance in renewing her DEA registration from Kristen Schmitt, who is a pharmacist and the Chief of Pharmacy Service for the Cincinnati VA Medical Center. (Gov't Ex. 7). The Government points to a short excerpt from the email conversation between Defendant and Schmitt in which Defendant states: "I only prescribe in the VA." The Government maintains that this statement demonstrates that Defendant knew that the November 2, 2013 prescription she wrote for Diazepam for K.H. was not authorized by her DEA registration. However, a review of the entire conversation between Defendant and Schmitt makes it clear that Defendant made the statement that she "only prescribe[s] in the VA" to explain to Schmitt that Defendant qualified for a fee-exempt DEA registration.[6] Whether Defendant qualified for a waiver of the fee to register is distinct from what prescriptions Defendant is authorized to write by her registration.

Viewing this evidence in a light most favorable to the government, this Court concludes that no rational trier of fact could have found the essential element of knowledge beyond a reasonable doubt. As such, a conviction of Defendant under the "registration" theory cannot stand.

[6]For instance, Schmitt began the conversation in her initial email to Defendant explaining where to find the form to start the renewal process. Schmitt then states: "I've been digging around on their website and what I can't find is whether or not you have to fill out the paper form in order to get your fee waived since you work for the VA." (Gov't Ex. 7).

As to the second theory, or the "legitimate course of practice" theory, Defendant argues that absent evidence of plainly improper prescribing practices, the Government was required to present expert opinion testimony.

In *United States v. Word,* 806 F.2d 658 (1986), the Sixth Circuit addressed this specific issue. After surveying a number of cases, the court concluded:

> The above cases indicate that while expert testimony as to "legitimate medical purpose" and "in the usual course of professional practice" may be helpful to a jury, there are cases in which the lay testimony is so clear that no expert testimony is required to determine that the defendant's actions were not for a legitimate medical purpose nor in the usual course of professional practice.

Id. at 663 (citing *United States v. Bartee*, 479 F.2d 484 (10th Cir. 1973); *United States v. Larson*, 507 F.2d 385, 387 (9th Cir. 1974); and *United States v. Rogers*, 609 F.2d 834, 839 (5th Cir. 1980)). Therefore, in cases alleging a violation of 21 U.S.C. § 841(a) against a physician, expert testimony that the defendant wrote the prescription at issue without legitimate medical purpose and outside the scope of usual professional practice is required, unless there is evidence of plainly improper prescribing practices that a lay juror could recognize as illegitimate. 806 F.2d at 663-64.

The evidence of plainly improper prescribing practices which was present in *Word* and the cases cited therein does not exist in the instant case. The lay testimony in *Word* included testimony that the defendant sold great quantities of Dilaudid for large sums of money. *Id*. at 663. The defendant dispensed his prescriptions at various locations. *Id*. Further, the defendant admitted he wrote prescriptions for various individuals without physical examination, often based merely upon their request for a specific drug. *Id*. One witness testified that he had told the doctor he intended to sell the pills. *Id*. at 663-64. There was evidence the defendant wrote prescriptions in return for sums of money

ranging between $200.00 to $1,000.00 for each prescription and accepted payment of $300.00 to $600.00 for prescriptions that he knew were intended for resale. *Id*. at 664. There was also evidence that the defendant often wrote the prescriptions at service stations, in vans or restrooms. *Id.*

Similarly, in *United States v. Elliott*, 876 F.3d 855 (6th Cir. 2017), three defendants, including one physician, were involved in a Florida pain center that generated millions in profits. *Id*. at 858. Roughly 20% of the pain center's patients, or 1,800 people, were Kentucky residents who traveled to the clinic for prescriptions to obtain opioid pills to sell in Kentucky. *Id*. at 858. Through lay testimony, the government introduced evidence that the physician prescribed the opioids in doses generally not found outside of patients with traumatic injuries or in end-of-life care. *Id*. at 864. There was also evidence that even though the physician thought the clinic's operation raised the "red flags" of a pill mill, the physician continued to work there. *Id*. The jury also heard about the extremely short time the physician spent with patients and her knowledge of the great distances patients were traveling to obtain prescriptions. *Id*. The Sixth Circuit concluded that based on this evidence, the jury did not require specific expert assistance to guide its decision-making as to the physician's culpability. *Id*. at 864-65.

Other examples of evidence of plainly improper prescribing practices that a lay juror could recognize as illegitimate include:

> (1) prescriptions issued for use by one patient but in the name of another patient; (2) admissions by patients that drugs would be used for nonmedical purposes, or "to get high," or that patients had no medical need for drugs but merely "liked them" or were "out of them"; (3) falsification of patient records, or requiring patients to use false names and identifications when filling prescriptions; (4) gigantic numbers of prescriptions written in a short period of time (e.g., 5,000 prescriptions in four months); (5) dispensing prescriptions without taking any medical history, conducting any

> examination, and in some cases without even meeting patients; and (6) prescribing drugs in return for incidental services by patients unrelated to any medical treatment.

United States v. Binder, 26 F. Supp. 3d 656, 662 (E.D. Mich. 2014) (citing *United States v. Varma*, 691 F.2d 460, 464 n. 2 (10th Cir. 1982) (collecting cases)).

Because no such evidence was presented in this case, the Government was required to present expert testimony to support a conviction based on its "legitimate course of practice" theory. However, a review of the evidence presented by the Government shows that no physician testified that the prescription for Diazepam which Defendant wrote for K.H. on November 2, 2013 was without a legitimate medical purpose.

It is undisputed that K.H., who did not testify, was seen by Dr. Muhammad A. Munir, M.D. at the behest of Defendant. Dr. Munir testified on behalf of the Government. Dr. Munir is board-certified in anesthesiology and pain management. (Doc. 67, PAGEID# 941). Dr. Munir has a private medical practice, but also works at the Cincinnati VA Medical Center. (Doc. 67, PAGEID# 937-938). In October, 2013, Defendant transported and introduced K.H. to Dr. Munir for the purpose of pain management. (Doc. 67, PAGEID# 963). Dr. Munir testified generally regarding the doctor-patient relationship in pain management and described his typical interactions with patients with regards to the medications he prescribes. (Doc. 67, PAGEID# 945-949). Dr. Munir also testified as to various drug interactions, including Diazepam. (Doc. 67, PAGEID# 956-958).[7]

With regards to K.H. specifically, Dr. Munir testified that when K.H. came to see him, K.H. had chronic, intractable pain, and had also recently fallen and suffered a fracture. (Doc. 67, PAGEID# 961). When describing K.H.'s medication history, Dr. Munir

[7]In his testimony, Dr. Munir referred to Diazepam by its generic name, Valium.

initially incorrectly testified that Defendant wrote the prescription in Count 3 on the date it was filled: November 29th. Dr. Munir testified that this caused him concern because this would have meant that Defendant wrote a prescription for Diazepam shortly after K.H.'s primary care physician, Dr. Paula Lafranconi, had also written a prescription for K.H. for Diazepam. (Doc. 67, PAGEID# 968). However, Dr. Munir's testimony is contradicted by Government's Exhibit 9, which is the OARRS report Dr. Munir ran on January 3, 2014 and shows the prescriptions for controlled substances reported for K.H. between January 1, 2012 and January 3, 2014. (Gov't Ex. 9; Doc. 67, PAGEID# 965). Government's Exhibit 9 shows that Defendant wrote the prescription on November 2, 2013, but K.H. did not fill the prescription until November 29th. At a sidebar conference, the Court and counsel discussed the discrepancy between Dr. Munir's testimony and Government's Exhibit 9. The Government then directed the correction of Dr. Munir's prior testimony. (Doc. 67, PAGEID# 977). The correct dates were then confirmed on cross-examination. (Doc. 67, PAGEID# 993). Dr. Munir then acknowledged that if Defendant had looked at an OARRS report before writing the prescription on November 2nd, the report would not have shown the prescription written by Dr. Lafranconi because the prescription from Dr. Lafranconi was not filled until November 22, 2013. (Doc. 67, PAGEID# 993).

Dr. Munir testified that in January of 2014 he showed Defendant a copy of the OARRS report he ran on January 3, 2014. (Doc. 67, PAGEID# 978-979). Dr. Munir testified that he told Defendant that because he was taking over the treatment of K.H., Defendant should no longer write prescriptions for K.H. (Doc. 67, PAGEID# 980).[8] Dr.

[8]The Government argues that this conversation occurred in October of 2013 during K.H.'s first visit. At one point in his testimony, Dr. Munir did state that before K.H.'s first visit in October of 2013 he ran an OARRS report, noticed prescriptions written by Defendant and told Defendant during the first visit that he would be taking over the medication so Defendant does

Munir explained that it was "common practice" for him to communicate with another physician to make sure that they were both not prescribing medication for the patient. (Doc. 67, PAGEID #981). Dr. Munir testified that after he spoke to Defendant, she never wrote another prescription for K.H. (Doc. 67, PAGEID #980).[9] At no time did Dr. Munir testify that the Diazepam prescription in Count 3 was outside the course professional practice or without legitimate medical purpose.

Other evidence in the record also falls short of proving that the Diazepam prescription Defendant wrote for K.H on November 2, 2013 was outside the course of professional practice or without legitimate medical purpose. Government's Exhibit 9 shows that other treating physicians for K.H. routinely prescribed combinations of controlled substances on the same date or in close proximity to each other. Dr. Munir himself wrote a prescription for K.H. for Opana on October 14, 2013, a prescription for Oxycodone on November 11, 2013, and another prescription for Opana, Oxycodone and Zolpidem on December 16, 2013. (Gov't Ex. 9). The Court notes that Dr. Munir wrote these last three prescriptions even though K.H. had just filled the two prescriptions for Diazepam from Defendant and Dr. Lafranconi on November 22, 2013 and November 29, 2013. Further, the November 2, 2013 prescription in Count 3 was written for 180 tablets

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not need to prescribe medication for K.H. (Doc. 67, PAGEID# 963). However, Dr. Munir later testified that he did not "originally notice" the prescriptions written by Defendant when he ran the first report "[b]ecause usually when we print [the] OARRS report, we just print it for one year. When I saw her first in October and I printed [a] one year report, it did not have any of [Defendant's] prescriptions." (Doc. 76, PAGEID# 979). Therefore, according to Dr. Munir's own testimony, he could not have mentioned any prescriptions written by Defendant during the October of 2013 visit.

[9]In addition, the Government did not offer any testimony or documentary evidence, such as a later-dated OARRS report, which showed that Defendant wrote any prescriptions for K.H. after the prescription written on November 2, 2013.

of 10-milligram Diazepam. Government's Exhibit 9 shows that on March 6, 2012, and again on May 1, 2012, another physician wrote a prescription for 240 tablets of 10-milligram Diazepam along with prescriptions for 120 tablets of 20-milligram Oxycodone and Oxycontin. (Gov't Ex. 9). When viewed against the other prescriptions written for K.H., there is nothing in the record which would indicate that the November 2, 2013 prescription in Count 3 was outside the course of professional practice or without legitimate medical purpose.

As one district court has explained: "In cases lacking such indicia of the absence of a legitimate medical purpose that even a lay juror could recognize, a directed verdict of acquittal is proper if expert evidence is not presented, because the jury has no reasonable basis on which to conclude beyond a reasonable doubt that the defendant acted outside the course of professional practice." *United States v. Binder*, 26 F. Supp. 3d 656, 662 (E.D. Mich. 2014) (citing *United States v. Shultice*, No. 98–54, 2000 WL 34030842, at *5 (N.D. Iowa Apr. 4, 2000) (noting that "[t]his is not the type of case that can be decided without expert testimony" and "[e]xpert medical evidence is required for a jury to ascertain and appreciate what type of conduct is and what type of conduct is not within the usual course of medical practice, and what type of conduct is without any legitimate medical purpose")). In this case, a reasonable juror could not fairly conclude based on the testimony of Dr. Munir or any other evidence in the record that Defendant wrote the prescription in Count 3 outside the course of professional practice or without legitimate medical purpose.

After reviewing the evidence in the light most favorable to the Government, the Court concludes that the Government failed to present sufficient evidence to support a

conviction under either the "registration" or the "legitimate course of practice" theory. Accordingly, Defendant Barbara Temeck's Motion for Acquittal (Doc. 71) is **GRANTED**.

C. Motion for a New Trial

Under Rule 29(d)(1), this Court must now "conditionally determine whether any motion for a new trial should be granted if the judgment of acquittal is later vacated or reversed." As explained above, this Court will analyze Defendant's motion for a new trial based on manifest-weight-of-the-evidence grounds.

Before trial, this Court ruled that the Government had the burden of establishing that Defendant wrote the prescription for K.H. knowing that she was not registered to write a prescription for that drug. (Doc. 40). As explained several times above, the Court instructed the jury that Defendant could be convicted under one of two theories: (1) Defendant wrote the prescription for K.H. "knowing that she was not authorized by her registration" to do so; or (2) Defendant was authorized, but Defendant wrote the prescription for K.H. without a legitimate medical purpose. (Doc. 58).

Even though the Court made it clear that the Government had to prove that Defendant knew the act of writing the prescription for K.H. was not authorized by her DEA registration, the Government presented its case as if a violation of the Controlled Substances Act could be based on strict liability. During the rebuttal portion of its closing argument, the Government stated:

> Ladies and gentlemen, there are two ways, not just the one that we heard so much about, about the medical care, there are actually two ways that Barbara Temeck can be found guilty. The first is that she wrote these prescriptions beyond the scope of her registration. Let's talk about that just for a second, actually more than a second.
>
> . . .

> The third prescription was also outside the scope of the registration because, again, she wasn't a patient at the VA. Now, she may have been scheduled by -- around other appointments by Dr. Temeck, but she wasn't a patient.
>
> And, by the way, I ask you to think, just because – I mean, she called it in and wrote the prescription or she called in a prescription. She didn't have any more authority to do that than a cab driver at this point, quite honestly. It may sound funny, but you need a license to write it. You can't write it. She has no more authority than you have to call it in for your kids. It's not registered. And it may sound funny that a doctor who is not registered, but that's the facts. Think about it as a cab driver. A cab driver has a license to move people around, just like an airline pilot. The cabbie can't fly the plane.
>
> That's all there is. It's as simple as that.

(Doc. 64, PAGEID# 903-904).

The Government continued to adhere to its "strict liability" view of the case during oral argument on the present Motion. The regulations for DEA registration are contained in 21 C.F.R. Part 1301. In response to a direct question from the Court, the Government stated that a registration violation of 21 C.F.R. § 1301 was a strict liability offense with no *mens rea* requirement. The language of 21 C.F.R. § 1301 does not support this contention.

Under this regulation, "[e]very person who manufactures, distributes, dispenses, imports, or exports any controlled substance or who proposes to engage in the manufacture, distribution, dispensing, importation or exportation of any controlled substance shall obtain a registration unless exempted by law or pursuant to §§ 1301.22 through 1301.26." 21 C.F.R. § 1301.11(a). Under 21 C.F.R. §1301.21, individual practitioners who are required to obtain an individual registration in order to carry out his or duties as an official of an agency of the United States are exempt from certain fees. It is possible that the nonpayment of the fee could lead to registration restrictions,

suspension or revocation. *See* 21 C.F.R. § 1301.36. However, DEA Agent Christopher Kresnak testified on behalf of the Government that after Defendant voluntarily surrendered her DEA registration, the DEA did not open a case on the matter and did not pursue it any further. (Doc. 83, PAGEID# 1379-1380).

Moreover, the Government has not provided, and the Court has not found, any cases where an unknowing violation of the DEA registration requirement formed the basis of a violation of the Controlled Substance Act. Instead, the Sixth Circuit has found that a 21 U.S.C. § 841(a) violation requires both general and specific intent. *United States v. Gibbs*, 182 F.3d 408, 433 (6th Cir. 1999) (citing *United States v. Pope*, 561 F.2d 663, 670 (6th Cir. 1977)); *see also United States v. Pope*, 561 F.2d 663, 670 (6th Cir. 1977) (explaining that Section 841(a)(1) "is violated only if possession is accompanied both by knowledge of the nature of the act and also by the intent 'to manufacture, distribute, or dispense.'") (quoting *United States v. Jewell*, 532 F.2d 697, 698 (9th Cir. 1976)).

The Government's statements during closing argument ignored an important element which it had the burden of proving: that Defendant knew the act of writing the prescription for K.H. was not authorized by her registration. While these statements may not rise to the level of "reversible error or violation of the defendant's substantial rights" under Rule 33's "interest of justice" standard, this Court does find that grounds for new trial do exist because the jury's verdict was against the manifest weight of the evidence.

Under the "registration" theory, the Government argued that Defendant knew she was acting outside the parameters of her DEA registration based on language found on the face of the registration itself. In closing argument, the Government explained that "[t]he DEA made it easy for her. They wrote it explicitly on the license." (Doc. 64,

PAGEID# 895). The Government referenced the phrase "For Official Duties Only" six times during its closing argument. (Doc. 64, PAGEID# 877, 878, 885, 886, 887, 888). This phrase did appear on one of Defendant's DEA registration certificates, which reads: "Restricted to Government personnel for official duties only." (Gov't Ex 6). However, this particular DEA registration was not in effect at the time Defendant wrote the prescription for K.H. The registration in effect at that time contains different restrictive language: "This registration is only for use at Federal or State institutions." (Gov't Ex 5). This is analogous to waving the wrong gun around in closing argument in a felon in possession case.[10]

At trial, Defendant testified that she was registered with the DEA to prescribe controlled substances throughout her career. (Doc. 81, PAGEID# 1149). Defendant maintained the same DEA registration number since the early 1980's. (Doc. 81, PAGEID# 1150). For many years she paid the registration fee herself, and then found out in 2004 that because she worked for the VA, she was exempt from paying the fee. (Doc. 81, PAGEID# 1154-1157). Defendant testified that other than confirming her name and DEA number were correct, Defendant did not read the DEA registration certificates.

[10]Defendant also takes issue with three other statements made by the Government in closing argument. The first statement was referring to K.H. as a "bedridden potential addict." (Doc. 64, PAGEID# 898). The second statement is that Defendant was on the VA's "compliance committee" and that the function of the committee was to "make sure people's licenses were appropriate." (Doc. 64, PAGEID# 905). The third statement was that Defendant "may have caused a lot of harm." (Doc. 64, PAGEID# 905). These statements were not supported by evidence presented at trial. Therefore, these statements were improper. However, counsel for Defendant objected after each instance (Doc. 64, PAGEID# 898, 904, 905). The Court then admonished the jury that the arguments of the lawyers are not evidence and the jury was to decide what the facts show. (Doc. 64, PAGEID# 902, 904). In one instance, the Court specifically told the jury "there is nothing in evidence as to that." (Doc. 64, PAGEID# 905). The Court notes that "juries ordinarily are presumed to follow the court's instructions." *Simmons v. South Carolina*, 512 U.S. 154, 171, 114 S. Ct. 2187, 2197, 129 L. Ed. 2d 133 (1994) (quoting *Greer v. Miller*, 483 U.S. 756, 766, n. 8, 107 S.Ct. 3102, 3109, n. 8, 97 L.Ed.2d 618 (1987)). Moreover, these statements were only tangentially related to the elements the Government was required to prove.

(Doc. 81, PAGEID# 1158-1159). The Court finds Defendant's testimony credible. On cross examination, DEA Agent Christopher Kresnak was asked:

> Q. . . . My question is: It's entirely possible that that certificate, it has the same number that they've always had, it's just getting re-upped for three years, being sent to their place of employment, a huge hospital in some circumstances, the registrant may never see that new hard copy registration, right?
>
> A. I guess that's possible.
>
> Q. Well, let's -- if they -- if they continued to write controlled substances, all they need for purposes of writing a prescription is the DEA number, correct?
>
> A. That's correct.

(Doc. 83, PAGEID# 1371). Therefore, the Court concludes the evidence presented at trial in support of the Government's "registration" theory weighs heavily against the verdict. The only evidence the Government presented that Defendant had any knowledge of what was authorized by her registration was the language on the face of the registration itself. However, instead of pointing to the registration which was in effect at the time the prescription was written, the Government repeatedly pointed to a registration which was issued after Defendant wrote the November 2, 2013 prescription for Diazepam for K.H. This led the jury to render a verdict that was against the manifest weight of the evidence.

The Court reaches the same conclusion based on the evidence presented at trial in support of the Government's "legitimate course of practice" theory.

The Sixth Circuit has explained that a jury must consider the following when determining whether a physician has violated the Controlled Substance Act:

> If a physician dispenses a drug in good faith in the course of medically treating a patient, then the doctor has dispensed the drug for a legitimate medical purpose in the usual course of accepted medical practice. That is, he has dispensed the drug lawfully.

> "Good faith" in this context means good intentions and an honest exercise of professional judgment as to a patient's medical needs. It means that the defendant acted in accordance with what he reasonably believed to be proper medical practice.

United States v. Volkman, 736 F.3d 1013, 1021 (6th Cir. 2013), *vacated on other grounds*, 135 S. Ct. 13, 190 L. Ed. 2d 286 (2014).[11] Based upon this statement of the law by the Sixth Circuit, the Court in this case instructed the jury:

> One aspect of the is defense that Barbara Temeck treated her patient in good faith. If a physician dispenses a drug in good faith in the course of medically treating a patient, then the doctor has dispensed the drug for a legitimate medical purpose in the usual course of accepted medical practice. That is, she has dispensed the drug lawfully.
>
> "Good faith" in this context means good intentions and an honest exercise of professional judgment as to a patient's medical needs. It means that the defendant acted in accordance with what she reasonably believed to be proper medical practice. In considering whether the defendant acted with a legitimate medical purpose, you should consider all of the defendant's actions and the circumstances surrounding them.

(Doc. 58, PAGEID# 804-805).

At trial, Dr. James Murphy, M.D, testified on behalf of Defendant. (Doc. 63, PAGEID# 829). Dr. Murphy is a pain management and addiction specialist. (Doc. 63, PAGEID# 829). Dr. Murphy reviewed test reports and prescription records for K.H. (Doc. 63, PAGEID# 831). Dr. Murphy was asked whether the prescription Defendant wrote for Diazepam, also known as Valium, for K.H. on November 2, 2013 was medically necessary. (Doc. 63, PAGEID# 833). Dr. Murphy testified:

[11]While the Supreme Court vacated the physician's convictions for unlawful distribution of controlled substances leading to death and remanded for consideration of the "but-for causation" standard, the Court explained its order has no bearing on petitioner's other convictions for conspiracy to unlawfully distribute a controlled substance, unlawful distribution of a controlled substance, maintaining a drug-involved premises, and possession of a firearm in furtherance of a drug-trafficking offense. *Volkman v. United States*, 135 S. Ct. 13, 14, 190 L. Ed. 2d 286 (2014).

> Well, based upon what I've heard today and what I read in the notes that I was given and then also looking at the OARRS report and seeing how the prescriptions have gone over time, this patient was physically dependent on the benzodiazepine, the Valium. It would make sense to me that a prescription like this would be written in this situation, and I have no reason to believe it was not medically necessary. It makes sense to me. Therefore, my inclination is that this was a medically necessary prescription.

(Doc. 63, PAGEID# 833-834). Dr. Murphy also testified that given the circumstances surrounding this prescription, the prescription was medically appropriate and written within the scope of usual medical practice. (Doc. 63, PAGEID# 834). On cross examination, Dr. Murphy testified that benzodiazepines, such as Valium, are mostly used for anxiety, but benzodiazepines also help with nerve damage pain so they are uniquely able to treat a number of different conditions. (Doc. 63, PAGEID# 853). Dr. Murphy testified that

> a lot of chronic pain patients have anxiety and depression as well. Does one cause one? Does one cause the other? They come hand in hand. So when you can treat both conditions, you can treat the muscle spasm as well as damaged nerves and anxiety together, then benzodiazepine becomes a good choice for that.

(Doc. 63, PAGEID# 854). Dr. Murphy explained that "a lot of primary care doctors feel comfortable writing Valium" because it has been around for a long time. (Doc. 63, PAGEID# 854). In addition, Dr. Murphy explained:

> it's technically a pretty safe drug. It has what's called a high therapeutic index. In other words, the dose that's therapeutic compared to the lethal dose is very far.

(Doc. 63, PAGEID# 854). Based on this testimony, the Court finds that in writing the November 2, 2013 prescription for Diazepam for K.H., Defendant acted in accordance with what she reasonably believed to be proper medical practice. The Court concludes that to the extent the jury's verdict on Count 3 was based upon Government's "legitimate

course of practice" theory, the jury's verdict that was against the manifest weight of the evidence

Accordingly, this Court conditionally determines that if the judgment of acquittal is later vacated or reversed, Defendant's motion for a new trial should be granted.

Based on the foregoing conclusion, the Court finds it unnecessary to address Defendant's Alternative Motion for Reconsideration of the Court's Order denying Defendant's Motion to Dismiss for Selective Prosecution.

IT IS SO ORDERED.

/s/ Michael R. Barrett
JUDGE MICHAEL R. BARRETT